UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/116,873	09/03/1993	GREGOR J. SUTCLIFFE	SCRF32.0DIV1	6883

7590 02/06/2004

WELSH AND KATZ, LTD.
120 SOUTH RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 6066

EXAMINER	
BROWN, TIMOTHY M	
ART UNIT	**PAPER NUMBER**
1648	19

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/116,873	SUTCLIFFE, GREGOR J.	
	Examiner	Art Unit	
	Tim Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-30,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-30, 32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This non-final Office action is responsive to the Remand to the Examiner mailed March 27, 2002 (hereinafter "Remand"). In the Remand (page 7), the Board noted the prosecution record was not in proper condition for appeal. The Board indicated that an Office Action may be issued to clarify the prosecution record. Accordingly, prosecution is reopened according to the provisions of 37 C.F.R. § 1.198.

Response to Arguments

In their response submitted April 11, 1995, Applicant argues the specification enables the full scope of his invention. Paper no. 7, page 6 et seq. The Examiner respectfully disagrees.

First, the Examiner notes Applicant's claims are directed to cDNA encoding any and all proteins that are expressed exclusively in the brain. Applicant's invention further provides that each cDNA encodes a protein that is capable of neuroactive function. Thus, in order to enable the full scope of Applicant's invention, the disclosure must demonstrate to one having ordinary skill, how each protein that is exclusive to the brain may be used to impart a neuroactive function. The Examiner submits Applicant has not met this burden. For example, myelin, which is produced in the brain, but not the tissues excluded by the invention, does not possess a neuroactive function per se. Consequently, Applicant's disclosure fails to enable the full scope of Applicant's invention.

Second, undue experimentation is required in order for one having ordinary skill to make and use Applicant's invention. Applicant points to Hybritech Inc. v. Monoclonal

Antibodies, Inc. for the proposition that his disclosure is enabling despite the level of experimentation required. Remand, page 9. In Hybritech, the court found the isolation of a broad range of claimed antibodies did not require undue experimentation. Unlike the present case, the isolation of Hybritech's antibodies required much less experimentation. For example, Hybritech's antibodies could be isolated using a column having the desired ligand, and subsequently eluting the column. In contrast, much more experimentation is required for Applicant's invention. First, every mRNA that is expressed in the brain must be isolated and then compared to nearly every other mammalian tissue using hybridization probes to determine which mRNAs are expressed exclusively in the brain. Of course, this would require that a probe be synthesized for each mRNA that is detected in the brain. Then, each protein that is found to be exclusively expressed in the brain would have to be evaluated for neuroactive function using binding assays and other pharmacological techniques. This procedure presents a great deal more experimentation than the isolation of antibodies performed in Hybritech. Thus, contrary to the court's finding in Hybritech, Applicant's disclosure has not enabled one of ordinary skill to make and use his invention without undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26-30, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 26-30 are directed to a cDNA of about 500 to 1800 nucleotides that encodes a "neuroactive" proteinoid and which is expressed exclusively in the brain. Assuming the term "neuroactive" is defined as having neurotransmitter function, Applicant's disclosure fails to enable his invention.[1]

While it is true Applicant's disclosure teaches four specific clones (p1A75, P1B236, 1B208 and p0-40), it falls short of demonstrating these clones express neuroactive proteins. Applicant's specification (page 44) admits the evidence that clone p1B236 is produces neuroactive proteinoids is "circumstantial and preliminary" based on the data. Moreover, in the Remand (page 6), the Board stated the activity of the recited proteinoids "appears to be, at best, based on circumstantial evidence." Finally, it appears the data in Applicant's disclosure only confirms the expression of the cloned proteins and their relative distribution in the brain. *See eg.* Figs. 1A-B. The disclosure offers no data that shows the cloned proteinoids have neuroactive function. Consequently, Applicant's disclosure fails to teach one of ordinary skill how to make and use the claimed proteinoid cDNA.

---

[1] It is assumed the term "neuroactive" defines having neurotransmitter function only for the purpose of analysis under 35 U.S.C. § 112, first paragraph. The term "neuroactive" is otherwise indefinite and fails to claim Applicant's invention with particularity as required by 35 U.S.C. § 112, second paragraph. See *infra.*

It is also noted that even if the specification were enabling with respect to clones p1A75, P1B236, 1B208 and p0-40, the specification does not reasonably provide enablement for the full scope of the claimed invention. This results from the fact that claim 26 is directed to any cDNA that is expressed exclusively in the brain. Moreover, the specification does not provide any data beyond that relating to clones p1A75, P1B236, 1B208 and p0-40.[2] Thus, the specification could not possibly demonstrate that every proteinoid that is expressed exclusively in the brain is neuroactive. Consequently, Applicant's disclosure fails to enable the full scope of his invention.

Claims 32 and 33 also lack enablement as required by 35 U.S.C. § 112, first paragraph. Claims 32 and 33 are directed to an mRNA that is expressed exclusively in the brain, and encodes a protein capable of neuractive function. By analogy to the discussion of the cDNA of claims 26-30, Applicant's disclosure does not demonstrate that each and every mRNA that is expressed exclusively in the brain is capable of neuroactive function. Thus, Applicant's disclosure fails to enable the mRNA recited in claims 32 and 33.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[2] The Examiner notes the disclosure fails to provide any evidence that clones p1A75, P1B236, 1B208 and p0-40 have any neuroactive function. The argument that the disclosure fails to enable the full scope of the invention is offered in the alternative only.

Claims 26-30, 32 and 33 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 26, 29 and 32 each recite "encoding a neuroactive proteinoid." The term "neuroactive" renders the scope of the claims indefinite because one skilled in the art would not know what biological activity is described by this term. Furthermore, the specification fails to provide any clarity to the meaning of "neuroactive." The Board also noted the term "neuroactive" was indefinite and lacked any clarification in the specification. Remand, page 5. Consequently, claims 26-30, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph for failing to particularly point out and distinctly claim Applicant's invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (703) 305-1912. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Tim Brown
Examiner
Art Unit 1648

tb
January 15, 2004

TB

James C. Housel

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

1/21/04